IN THE
UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

PATTI POKORNY AND CHRISTOPHER POKORNY (H/W), Plaintiffs, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 4:14-cv-02960

DEFENDANT'S MEMORANDUM OF LAW
IN OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL

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Plaintiffs Patti and Christopher Pokorny have admitted that this discovery dispute relates to a narrow question: what information sales representatives employed by Defendant Eli Lilly and Company ("Lilly") communicated to Plaintiff Patti Pokorny's doctors about the potential risk of discontinuation symptoms upon stopping Cymbalta therapy. Lilly has proposed to respond to that question in two ways. First, Lilly has produced a wide range of documents relating to Lilly's promotion and marketing of Cymbalta, including marketing materials provided to prescribing doctors, information on sales representative training, and data on sales calls by Lilly representatives to Ms. Pokorny's prescribing doctors. Second, Lilly has offered to conduct a targeted search of the email files of the 13 sales representatives at issue to identify responsive documents.

Plaintiffs' motion seeks much more. Their request purports to seek production of so-called "custodial files" — effectively every piece of paper, email, and other electronic document — regardless of content, sensitivity, or relevance — for 13 Lilly sales representatives. Plaintiffs declined Lilly's offer during the meet-and-confer process to discuss search terms that might be applied to the relevant email files to capture documents relevant to their specific claims. Instead, they have maintained that Lilly must produce all documents maintained in the sales representatives' files, including facially irrelevant materials relating to other Lilly products, other healthcare providers, or confidential personnel information.

Even if Plaintiffs could overcome the threshold relevance bar that the Federal Rules place on such a broad request, this indiscriminate foray violates the principles of proportionality animating the Federal Rules. Plaintiffs cannot justify a sweeping production of the electronic and hard copy files of 13 Lilly employees in light of the scope of Ms. Pokorny's alleged injuries. This Court has "wide discretion" to define the scope of discovery, taking into account the

importance of the issues at stake in the litigation, among other factors, and the importance of the proposed discovery to resolving those issues. Given the nature of the alleged injuries in this case, broad discovery of almost certainly irrelevant and potentially quite personal materials is unwarranted.

The Court should deny Plaintiffs' motion to compel.

BACKGROUND

I. Plaintiffs' Claims.

Cymbalta is an FDA-approved prescription medication used to treat various pain and psychiatric disorders. It is in a class of medicines known as serotonin-norepinephrine reuptake inhibitors (SNRIs). Plaintiffs' case is one of many pending across the country, each of which claims that Lilly failed to warn adequately of the risk of potential symptoms upon discontinuation of Cymbalta. Of the cases litigated to a merits determination, Lilly has won summary judgment in two suits (including on the adequacy of the Cymbalta discontinuation warning) and prevailed in three trials involving four plaintiffs, including securing a jury finding that the Cymbalta warning was adequate. *See Hagan-Brown v. Eli Lilly & Co.*, 1:14-cv-01614-AJT-JFA (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Ali v. Eli Lilly & Co.*, 1:14-cv-01615 (AJT/JFA) (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Herrera v. Eli Lilly & Co.*, No. 2:13-cv-02702 (C.D. Cal. Aug. 10, 2015) (defense verdict for Lilly on all claims); *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-02701-SVW-MAN (C.D. Cal. Aug. 18, 2015) (directed verdict for Lilly entered at close of plaintiff's case); *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391 (S.D.N.Y. 2014) (granting judgment for Lilly on adequacy of warning), *reconsideration denied* 2015 WL 845720 (S.D.N.Y. Feb. 26, 2015); *Carnes v. Eli Lilly & Co.*, No. 0:13-591-CMC, 2013 WL 6622915 (D.S.C. Dec. 16, 2013) (granting summary judgment to defendant).

An inherent risk of stopping any antidepressant therapy is the potential for a patient to experience certain unwanted effects, which the medical community describes as "discontinuation" symptoms. The medical community understands the potential for these symptoms, practice guidelines discuss this risk, and all antidepressant labeling includes information about this phenomenon. Since Cymbalta was first approved by the U.S. Food and Drug Administration ("FDA") in 2004, its label has included a detailed, three-paragraph warning about the risk of discontinuation symptoms. The label in place at the time of Plaintiff's prescriptions was approved by the FDA in 2005 and stated:

> Discontinuation of Treatment with Cymbalta
>
> Discontinuation symptoms have been systematically evaluated in patients taking Cymbalta. Following abrupt discontinuation in MDD placebo-controlled clinical trials of up to 9-weeks duration, the following symptoms occurred at a rate greater than or equal to 2% and at a significantly higher rate in Cymbalta-treated patients compared to those discontinuing from placebo: dizziness; nausea; headache; paresthesia; vomiting; irritability; and nightmare.
>
> During marketing of other SSRIs and SNRIs (serotonin and norepinephrine reuptake inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. Although these events are generally self-limiting, some have been reported to be severe.
>
> Patients should be monitored for these symptoms when discontinuing treatment with Cymbalta. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate (*see* DOSAGE AND ADMINISTRATION).

Cymbalta Package Insert at 9-10 (October 2005), Ex. 1.

II. The Discovery Dispute at Issue

Plaintiffs have requested and received from Lilly the names of the various Lilly sales representatives who made Cymbalta-related calls on four of Ms. Pokorny's doctors from the launch of the medication through the present. They have now moved to compel with respect to two Requests for Production — Nos. 91 and 95 — asserting that these two requests amount to the custodial files of the 13 sales representatives enumerated in Plaintiffs' motion. Memorandum of Law in Support of Plaintiffs' Motion to Compel at 6, 8. In its May 12, 2015 Objections and

Responses to Plaintiffs' First Set of Requests for Production of Documents, Lilly objected to these requests on numerous grounds. Lilly objected to Request for Production No. 91, which asks for confidential personnel information, such as employment agreements, termination agreements, performance reviews, self-reviews, W-2s, and bonus amounts as follows:

> Lilly objects to this Request as overly broad and unduly burdensome as to time and scope. Lilly also objects to this Request as it is not limited to documents relating to Cymbalta or any alleged discontinuation-emergent adverse events potentially arising from Cymbalta treatment and therefore seeks information that is neither relevant nor likely to lead to the discovery of admissible evidence. To the extent this Request involves confidential personnel information, Lilly further objects to this Request as unduly infringing on the privacy rights of its employees. The precise dollar amounts of Lilly's compensation to its employees and their performance reviews are not relevant to this litigation and Plaintiff's request would cause undue annoyance and embarrassment to these employees.

Defendant's First Amended Objections and Responses to Plaintiffs' First Set of Requests for Production of Documents (May 12, 2015), Ex. 4.

Lilly objected to Request for Production No. 95, which asks for "marketing materials, brochures, sales aids, "slim jims," "skiffs," clinical trials / medical journal articles, PowerPoint presentations, etc., that were given or shown by LILLY pharmaceutical representatives" to Ms. Pokorny's medical providers as follows:

> Lilly objects to this Request as not limited to documents relating to Cymbalta and to the extent records of any documents or marketing materials given or shown by Lilly pharmaceutical representatives to all the above-identified medical professionals are not contained in Lilly's sales database. Subject to and without waiving its foregoing objections, Lilly responds that the information in its sales database does not indicate which marketing materials or other documents were shown to particular medical professionals.

Id.

A. Lilly's Extensive Production of Marketing and Promotional Materials

Lilly has already produced more than 35,000 pages of documents related to the issues here and has agreed to produce many more upon a reasonably diligent search, including:

- All advertisements and promotional materials directed at either health care professionals or consumers, as submitted to the FDA's Office of Prescription Drug Promotion, consisting of more than 15,000 documents;
- Lilly's Dear Healthcare Professional letters concerning Cymbalta;
- Documents reflecting inquiries from health care professionals and consumers to Lilly about Cymbalta discontinuation;
- Medical information letters concerning Cymbalta and discontinuation-emergent adverse events;
- Cymbalta brand plans;
- Market surveys and related materials concerning Cymbalta and discontinuation-emergent adverse events;
- Most recent training materials for sales representatives;
- Exemplars of packaging and accompanying materials for samples of Cymbalta;
- Health-care-provider-level prescription data for Plaintiff's doctors as identified by Plaintiff;
- Records from Lilly's incentive compensation system reflecting performance-based metrics for the sales representatives that called on Plaintiff's doctors;
- Spreadsheets tracking sales calls to Plaintiff's doctors;
- Records of any compensation paid to Plaintiff's doctors;
- Written agreements, contracts, liability releases, or legal documents between Lilly and Plaintiff's doctors; and

- Records of attendance by Plaintiff's doctors at Cymbalta-related programs sponsored by Lilly.

Id.

Many of these categories address the types of documents Plaintiffs seek from the sales representatives' files, particularly training materials, records from Lilly's incentive compensation system, sales call trackers, and advertising and promotional materials.

B. Lilly's Proposal to Produce Sales Representative Email Files

To address Plaintiffs' request for information on "what Lilly's employees communicated about Cymbalta to Plaintiff Patti Pokorny's doctors" through its sales representatives, Lilly offered on September 22, 2015 "to produce emails and attachments from these representatives for the identified time periods that relate to Cymbalta discontinuation or withdrawal." Meredith Gray Declaration, Ex. B. Lilly further proposed locating those relevant documents using a set of search terms that had been applied in related cases to the email files of other Lilly employees. *See id.* Indeed, search terms have been used to identify responsive documents for prior productions in related litigation, documents to which Plaintiffs have access. Lilly further indicated its willingness, in meet-and-confer discussions in this matter and in related cases, to produce documents involving Ms. Pokorny's doctors. Declaration of Emily Ullman, Appx. AA ¶ 8.

Lilly offered to work with Plaintiff's counsel to revise the list of search terms. Lilly noted its objection to producing every document associated with a given representative, noting that production of "all documents, whether electronic, paper, or email, for these representatives, not limited by relationship to the topics at issue in Ms. Pokorny's lawsuit" would constitute "a wide-ranging production, which goes beyond the limits of reasonable discovery." Meredith Gray Declaration, Ex. B. By contrast, Lilly's proposed search would provide Plaintiffs with any direct

communications with (or about) her healthcare providers by the relevant sales representatives and, for example, any directives to these sales representatives related to Cymbalta discontinuation or sales materials that included any discussion of Cymbalta discontinuation.

C. Plaintiffs Decline Lilly's Middle-Ground Proposal

Although Plaintiffs' claims relate solely to alleged symptoms arising from discontinuation of Cymbalta therapy, Plaintiffs took issue with Lilly's proposal to search for relevant documents, contending that electronic searches were not sufficient. Meredith Gray Declaration, Ex. C. Moreover, at a meet and confer between the parties, Plaintiffs questioned Lilly about the contents of representatives' files but refused to revise their demand to less than the entirety of the "custodial file" for each representative. Declaration of Emily Ullman, Appx. AA ¶ 10. Lilly additionally noted that the collection and review process Plaintiffs demanded was inherently burdensome, particularly as extended to physical and electronic documents stored outside the context of centralized emails. Declaration of Emily Ullman, Appx. AA ¶ 9. Without addressing Lilly's continued offer to revise search terms, Plaintiffs responded on September 25, 2015 that they would be seeking this Court's intervention. Meredith Gray Declaration, Ex. C.

In parallel to the discussions described above, counsel for Plaintiffs moved to compel complete sales representative custodial files in a related Cymbalta discontinuation case in the District of Minnesota. *See McCabe v. Eli Lilly & Co.*, No. 0:14-cv-03132 (D. Minn.). On October 22, 2015, Magistrate Judge Keyes denied the plaintiff's motion in favor of requiring the parties to meet and confer further on search terms, calling the plaintiff's requests "grossly overbroad." Declaration of Emily Ullman, Appx. AA ¶ 11.

STANDARD OF REVIEW

"[I]t is well established that the district court has wide discretion in establishing the confines of discovery." *Global Sessions LP v. Travelocity.com LP*, No. 6:10cv671 LED–JDL,

2012 WL 1903903, at *1 (E.D. Tex. May 25, 2012). Discovery of non-privileged information is permissible if "'reasonably calculated to lead to the discovery of admissible evidence'" related to the claim or defense of any party. *Marin v. Gilberg*, No. V-07-62, 2009 WL 426061, at *1 (S.D. Tex. Feb. 19, 2009) (quoting Fed.R.Civ.P. 26(b)(1)). The party seeking discovery "bears the burden of showing that the materials and information sought are relevant to the action or will lead to the discovery of admissible evidence," and only when the moving party meets this burden does the burden shift to the opposing party to show the discovery is not relevant or is outweighed by potential harm. *Abraham v. Alpha Chi Omega*, 271 F.R.D. 556, 559 (N.D. Tex. 2010). Moreover, "practical considerations dictate that the parties should not be permitted to roam in shadow zones of relevancy and to explore matter which does not presently appear germane on the theory that it might conceivably become so." *Munoz v. State Farm Lloyds*, No. B-04-141, 2008 WL 4533932, at *2 (S.D. Tex. Oct. 9, 2008) (internal quotation marks omitted). To the contrary, parties have "'no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings.'" *Kaiser Aluminum & Chem. Corp. v. Willis of Md., Inc.*, No. Civ.A. 02-0944, 2003 WL 21750631 at *1 (E.D. La. July 28, 2003) (quoting Fed.R.Civ.P. 26(b)(1) advisory committee's note (2000)).

In weighing whether the discovery sought is proportional to the likely benefit, courts consider "'the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the proposed discovery in resolving these issues.'" *Doe v. Catholic Soc. of Religious and Literary Educ.*, No. H-09-1059, 2009 WL 4506560, at *1 (S.D. Tex. Dec. 3, 2009) (quoting Fed.R.Civ.P. 26(b)(2)(C)(iii)). "[C]ourts are obligated to limited discovery where 'the burden or expense outweighs its likely benefit.'" *Doe*, 2009 WL 4506560, at *1 (quoting Fed.R.Civ.P. 26(b)(2)(C)(iii)); *see also In re*

DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig., No. 3:11–MD–2244–K, 2013 WL 2091715, at *2 (N.D. Tex. May 15, 2013) ("the court may limit discovery of material, even if relevant, where 'the burden or expense of the proposed discovery outweighs its likely benefit'").

ARGUMENT

Although Plaintiffs have failed to define the term "custodial file," their motion to compel seeks production of the "custodial files" of 13 sales representatives, which amounts to a request for every piece of paper, electronic document, and email these individuals created, sent, or received during periods of time ranging from one month to almost six years. This requested discovery is, on its face, improper because it necessarily encompasses irrelevant and potentially sensitive employment and personnel information and is not proportional to the needs of this case. The search terms proposed by Lilly would address the relevance concerns raised by Plaintiffs' motion and, coupled with the expansive discovery already provided on Cymbalta sales and marketing, facilitate the production of a robust universe of relevant information on Plaintiffs' stated area of interest — "Lilly's employees' communications with Plaintiff Patti Pokorny's doctors" about Cymbalta. Pl. Memo. at 13.

I. Plaintiffs' Discovery Proposal Seeks Irrelevant Documents.

Plaintiffs' central premise is that "what Lilly communicated to [Plaintiff's] doctors about Cymbalta" is "highly relevant." Pl. Memo. at 10, 11. Consistent with its discovery obligations, Lilly has provided or agreed to provide documents speaking directly to this issue, including email correspondence from the sales representatives who interacted with Ms. Pokorny's doctors. Plaintiffs' motion goes far beyond the limits envisioned by the Federal Rules, however, to seek wholesale production of files that indisputably include information having no bearing on Plaintiffs' claims. As Magistrate Judge Keyes noted in the *McCabe* litigation, these discovery

requests are "grossly overbroad." Declaration of Emily Ullman, Appx. AA ¶ 11. The party seeking discovery "bears the burden of showing that the materials and information sought are relevant to the action or will lead to the discovery of admissible evidence." *Abraham*, 271 F.R.D. at 559. Moreover, "practical considerations dictate that the parties should not be permitted to roam in shadow zones of relevancy and to explore matter which does not presently appear germane on the theory that it might conceivably become so." *Munoz*, 2008 WL 4533932, at *2 (internal quotation marks omitted). Because Plaintiffs have not demonstrated the relevance to the claims of the broad brush discovery they seek here — including information on other Lilly products or sensitive personnel information — they have not carried their burden.

A. Information regarding other products is irrelevant.

The 13 sales representatives' files, unlimited by search terms, would include many documents related to other products and unrelated to Cymbalta. Lilly has performed initial collection and analysis of sales representative email files in a related matter, and preliminary results indicate that only approximately 20% of documents in representatives' email even mention Cymbalta or its generic name, duloxetine. Declaration of Emily Ullman, Appx. AA ¶ 6. Lilly records demonstrate that the territory to which Sales Representative Brooke Adams belonged detailed Axiron, a testosterone treatment, and Cialis, an erectile dysfunction medication, along with Cymbalta. Declaration of Emily Ullman, Appx. AA ¶ 7. In an apparent concession that the files they seek would require the production of information on products other than Cymbalta (as well as a variety of other topics), Plaintiffs now argue that discovery on the promotion of other Lilly products is relevant to their claims. This claim fails on two grounds.

First, documents related to other products cannot reasonably be anticipated to lead to admissible evidence. Relevant evidence makes a fact that is of consequence in determining the action more or less probable than it would be without the evidence. Fed. R. Evid. 401. Evidence

that is not relevant is not admissible. Fed. R. Evid. 402. In product liability suits, courts have routinely held that evidence related to other products does not satisfy this threshold relevance standard. *See, e.g.*, *Cross v. Wyeth Pharm., Inc*., No. 8:06-cv-429-T-23AEP, 2011 U.S. Dist. LEXIS 67348, at *19 (M.D. Fla. June 23, 2011) (excluding evidence of other product where plaintiff "never used the product"); *Hajek v. Kumho Tire Co.*, No. 08-CV-3156, 2010 WL 503044, at *8 (D. Neb. Feb. 8, 2010) (sustaining defendant's objection to overbroad and burdensome discovery requests where defendant limited document production to the type of tire in the subject accident); *Diaz v. Goodyear Tire & Rubber Co.*, No. 07-353-B-M2, 2009 WL 1298219, at *3 (M.D. La. May 8, 2009) (denying motion to compel to the extent it sought documents and information about types of tires other than that used in the subject accident); *Skibniewski v. Am. Home Prods. Corp*., 2004 WL 5628157, at *4 (W.D. Mo. Apr. 1, 2004) (granting motion to exclude evidence of defendant Wyeth's other products on grounds of relevance and impermissible character evidence and validating Wyeth's argument that "evidence relating to different drugs, different injuries, different people and different conditions have no bearing on this case."); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2003 WL 22798013, at *2 (E.D. Pa. 2003) (barring evidence even as to punitive damages of the amount or size of Wyeth's sales of other products as having "no relevance whatsoever" to whether the diet drugs in question caused the plaintiff's medical condition). This authority reflects the common sense principle that the product at issue in a failure-to-warn suit is the proper subject of evidentiary inquiry in resolving the merits of a plaintiff's claims. Here, Plaintiffs have alleged that other products may be relevant because a sales representative who promoted Cymbalta to Ms. Pokorny's doctors might have discussed "the risk of side effects or withdrawal *for other products*" with *other doctors*. *See* Pl. Mem. at

13. That such communications would have any relevance to actual communications between a representative and Ms. Pokorny's doctors is wholly speculative.

Second, while Lilly's promotional practices as to Cymbalta may potentially be relevant — and related documents would be captured by Lilly's proposed search terms so long as they touched on discontinuation issues — Lilly's promotional practices as a general matter across its products are not relevant to the issues in this case. This is particularly so where Plaintiffs have made no claim or showing that a generalized corporate practice influenced the company's promotion of Cymbalta. Indeed, it is worth noting that three trials involving four plaintiffs were tried to verdict without the need for the irrelevant and burdensome productions the Plaintiffs seek here. *See Hagan-Brown v. Eli Lilly & Co.*, 1:14-cv-01614-AJT-JFA (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Ali v. Eli Lilly & Co.*, 1:14-cv-01615 (AJT/JFA) (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Herrera v. Eli Lilly & Co.*, No. 2:13-cv-02702 (C.D. Cal. Aug. 10, 2015) (defense verdict for Lilly on all claims); *Hexum v. Eli Lilly & Co.*, No. 2:13-cv-02701-SVW-MAN (C.D. Cal. Aug. 18, 2015) (directed verdict for Lilly entered at close of plaintiff's case). Parties have "'no entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings.'" *Kaiser Aluminum & Chemical Corp.*, 2003 WL 21750631 at *1 (quoting Fed.R.Civ.P. 26(b)(1) advisory committee's note (2000)).

B. <u>Information on confidential personnel information is irrelevant.</u>

Documents such as performance reviews of individual sales representatives are also unconnected to the issues in this case and would unduly cause annoyance and embarrassment to these individuals without any apparent benefit to Plaintiffs. As discussed, Lilly has provided or agreed to provide metrics related to sales performance from Lilly's incentive compensation system, which addresses the incentives sales representatives have to promote a medicine.

Individualized employment information, including compensation, bonuses, and performance reviews is neither necessary nor relevant to the issues in this case. *See, e.g., Hexum v. Eli Lilly*, No. 2:13-cv-02701-SVW-MAN (C.D. Cal. Apr. 24, 2015), ECF No. 272 (Order denying Plaintiffs' request for disclosure of the "financial biases of Lilly corporate witnesses," specifically requesting salaries and the value of shares of corporate stock owned by witnesses who would testify at trial) (Ex. 5); *see also* ECF No. 255 (Plaintiffs' request for disclosure) (Ex. 6). Furthermore, these files may include confidential and sensitive business information, as well as sales representatives' personal information, which are also wholly irrelevant to Plaintiffs' case and which could be culled from production through the use of search terms.

II. Lilly Has Offered Extensive Information on "What Lilly Communicated to [Plaintiff's] Doctors About Cymbalta."

A. Lilly has produced extensive information on Cymbalta's marketing.

Plaintiffs' motion proposes to secure from the "custodial files" of the sales representatives at issue here documents such as "marketing materials," "performance reviews," and information related to Lilly's sales strategy. Pl. Memo. at 6-7, 12. Contrary to Plaintiffs' suggestion, Lilly has produced a robust universe of materials on Cymbalta's marketing and promotion, much of it touching on each of these categories, including:

- Advertisements and promotional materials — Lilly has produced over 15,000 documents comprising all advertisements and promotional materials directed either at healthcare professionals or consumers, as submitted to the FDA's Office of Prescription Drug Promotion.
- Spreadsheets tracking sales calls to Plaintiff's doctors — Lilly has produced spreadsheets showing every visit made by Lilly sales representatives and third-party

contractors (NovaQuest) to Plaintiff's prescribing physicians. These spreadsheets include details about the type of activity conducted at each visit.

- Cymbalta brand plans — Lilly has produced annual brand strategy documents developed by the Cymbalta brand team, which included marketing employees.
- Performance-based metrics from Lilly's incentive compensation system — Lilly has agreed to produce performance-based metrics that are used to determine the bonuses awarded to Lilly sales representatives.

Although Lilly does not concede the ultimate admissibility of these documents at trial, the materials, among others, go directly to the issues of ostensible concern to Plaintiffs — marketing and promotion of Cymbalta, the incentives sales representatives have to promote Cymbalta, and the actual contacts sales representatives had with Plaintiff's doctors.

In the face of this vast array of information, Plaintiffs fail to point to any material deficiency justifying the wide-ranging production they propose here.[1]

B. Lilly's search term proposal is an appropriate approach to identifying relevant documents here.

It is beyond serious dispute that the use of search terms is an established method of identifying relevant and responsive documents. *See Shipley v. Forest Laboratories*, No. 1:06-cv-00048-TC-DBP, 2014 WL 4270939, at *4 (D. Utah Aug. 29, 2014) (allowing defendants to

[1] Plaintiffs point to Lilly's objection that its sales database does not track which materials went to which doctors. The application of search terms to the relevant sales representatives' documents, including the names of Ms. Pokorny's doctors, would address this concern. Search terms would capture communications between the sales representatives and Ms. Pokorny's doctors, including materials shared with Plaintiff's doctors to the extent that such information is captured in a documentary record. Furthermore, sales materials distributed to representatives that included discussion of Cymbalta discontinuation or withdrawal would be captured by the proposed search terms — and because discontinuation is warned about extensively in the Cymbalta label, it is featured prominently in the vast majority of Cymbalta promotional materials. What Plaintiffs insist on seeking is material *unrelated* to the issue at hand that is *not* explicitly identified as having been communicated to Ms. Pokorny's particular doctors.

search sales representatives' documents with search terms and time limiters); *Peterson v. Seagate U.S. LLC*, 2009 WL 3430150, at *3 (D. Minn. Oct. 19, 2009) (denying Plaintiff's request for a copy of an individual's hard drive and instead directing the defendant to use agreed-upon search terms to produce "complete, nonprivileged information that is responsive to Plaintiff's request"). Moreover, Lilly has used search terms to identify responsive documents for prior productions in related litigation. The use of search terms here would permit Lilly to identify any email communications by the relevant sales representatives on Cymbalta discontinuation — the core issue in this suit — as well as any email correspondence specifically focused on Plaintiff's prescribers. Because the Cymbalta Package Insert includes a warning on discontinuation symptoms that includes the search terms proposed by Lilly, those terms will capture every document that contains a copy of the Cymbalta label, including all Cymbalta promotional materials and training materials about the medication.

Despite their tacit acknowledgment of this self-evident principle, Plaintiffs have refused to engage with Lilly regarding the development of a list of search terms appropriate to their claims. Their resistance on this point has prevented Lilly from proceeding with the search for responsive documents that they seek.[2] Indeed, although Plaintiffs criticize Lilly for its proposal of search terms more extensive than simply the word "Cymbalta," Pl. Mem. at 15, Plaintiffs have refused to put forth a "Cymbalta"-only counter-proposal and have maintained at all times that

[2] Plaintiffs cite the number of contacts sales representatives had with Plaintiff's health care providers as support for the production of these sales representatives' documents to "discover[] . . . what Lilly communicated to [Plaintiff's] doctors." Pl. Memo. at 10. Regardless of the number of contacts, however, reasonable search terms that include Plaintiff's doctors' names would identify any relevant communications.

only a production including irrelevant documents about other products will satisfy them.[3] Declaration of Emily Ullman, Appx. AA ¶ 10. Lilly remains willing to engage with Plaintiffs on the construction of a mutually-agreeable search term protocol that would address the topics on which they desire discovery. Finally, as noted above, the parties have been ordered to develop a search term protocol in the *McCabe* case in the District of Minnesota, and Lilly expects that such a protocol should be equally applicable in this matter.

III. Plaintiffs' Discovery Proposal Violates Principles of Proportionality

Even if the Court finds that documents unrelated to Cymbalta discontinuation or withdrawal are marginally relevant — and Lilly maintains that they are not — this Court must weigh whether the discovery sought is proportional to the likely benefit, considering "the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the action, and the importance of the proposed discovery in resolving these issues." *Doe*, 2009 WL 4506560, at *1 (quoting Fed.R.Civ.P. 26(b)(2)(C)(iii)). "[W]hen discovery requests approach the outer bounds of relevance and the information sought may only marginally enhance the objectives of providing information to the parties or narrowing the issues, the court must then weigh the request with the hardship to the party from whom the discovery is sought." *Piazza's Seafood World, L.L.C. v. Odom*, No. 07–413–BAJ–CN, 2011 WL 3664437, at *2 (M.D. La. Aug. 19, 2011).

[redacted]

[3] Plaintiffs further note that Lilly was, in related litigation, accused of improperly designing its search terms. Pl. Mem. at 16 n.6. The court in that case has denied the cited motion for sanctions on the grounds that sanctions were unwarranted. Minutes in Chambers Denying Pl.'s Mot. for Sanctions, *Saavedra v. Eli Lilly & Company*, No. 2:12-cv-9366 (C.D. Cal. Oct. 14, 2015), Dkt. 200 (Ex. 7).

[redacted] Each of Plaintiffs' claims hinge on the warnings associated with the design or promotion of Cymbalta and not Lilly's general promotional practices. Given the nature of Plaintiffs' alleged injuries, the marginal importance of the proposed discovery to these issues, and the hardship that would result from either a full review of the documents for relevance and privilege or a wholesale production of irrelevant and sensitive documents, broad discovery unlimited by search terms to identify documents related to Cymbalta should be denied.

Lilly's search term proposal addresses these significant proportionality concerns. Contrary to Plaintiffs' unsupported assertion, search terms are not "only warranted when the set of potentially relevant documents is so voluminous that reviewing the document set is otherwise unduly burdensome." Pl. Memo. at 18. This is not the case. Search terms are an appropriate, efficient methodology for identifying relevant documents in litigation that does not approach a massive scale. *See Peterson*, 2009 WL 3430150, at *3 (directing the use of search terms instead of the production of a copy of an individual's hard drive).

In any event, the full files sought here, including hard copy, email and electronic documents, even limited to the time periods proposed by Plaintiffs, which are as lengthy as almost six years, will undoubtedly be voluminous and burdensome to produce. The documents sought by Plaintiffs, for example, would necessarily include every email ever sent to, from, or copying the 13 sales representatives across an almost six-year period, whether related to Cymbalta or not, as well as any hard copy paper file maintained for those individuals. By way of example, Lilly quantified the email files of one of the sales representatives in related litigation, Ann Courington, for the requested period of time of September 1, 2004 through April 30, 2013. Her email files alone consist of approximately 160,000 emails and attachments (prior to any

potential de-duplication). The files of other sales representatives, over shorter time periods, also included tens of thousands of emails and attachments. Declaration of Emily Ullman, Appx. AA ¶¶ 4-5 .

The alternative to using search terms would be Lilly's review of each document for responsiveness and privilege — not an indiscriminate production of every electronic and hard copy document maintained in each sales representative's files. A document-by-document review, without the benefit of search terms, would be unduly burdensome, particularly where the proposed search terms would efficiently identify the relevant communications. And, indeed, "the use of key words has been endorsed as a search method for reducing the need for human review of large volumes of ESI." *Romero v. Allstate Ins. Co.*, 271 F.R.D. 96, 109 (E.D. Pa. 2010) (quoting 10 Sedona Conf. J. at 223).

Plaintiffs rely on a series of cases to support their claim to sweeping discovery of individual sales representative files. None speaks to the specific question before the Court here. First, Plaintiffs look to *Baker v. Bayer Healthcare Pharm. Inc.*, No. 13-cv-00490-THE (KAW), 2014 WL 5513854, at *2 (N.D. Cal. Oct. 31, 2014) to support their claim for broad discovery of sales representative files unlimited by search terms. Pl. Memo. at 16-17. In dispute in that case were geographic and time limitations. In granting discovery, the court noted that "sales call notes could … lead a jury to infer that Defendant's Mirena campaign was so pervasive that any doctor, including Plaintiff's, would fail to heed any warning about the product." There was no discussion of other products in that case and, indeed, only sales calls related to Mirena would be relevant to the pervasiveness of the defendant's Mirena campaign. Similarly, Plaintiffs' reliance on *Cunningham v. Smithkline Beecham*, 255 F.R.D. 474 (N.D. Ind. 2009), is misplaced. Pl. Memo. at 16. Again, in granting Plaintiff's request for sales files, the court focused on potential

evidence relevant to the medicine at issue in that case — Paxil. *Id*. at 479 (noting that plaintiff's request itself concerned whether the defendant "fraudulently represented the safety of *Paxil*" to the prescribing doctor). Because the court was not addressing the issue of irrelevant documents related to other products, the case has no bearing on the relevancy issue faced here.

Finally, Plaintiffs cite *In re Levaquin Prods. Liab. Litig.*, No. MDL 08-1943 JRT, 2009 WL 10424741, at *3 (D. Minn. Nov. 25, 2009) for the proposition that "any discoverable documents in the possession of sales representatives who called on bellwether plaintiffs' prescribing doctors, regardless of whether those sales representatives will be deposed" should be produced. Pl. Memo. at 17. Defendant agrees that Plaintiffs are entitled to "discoverable documents" in the files of the 13 sales representatives they have identified in their motion. However, documents unrelated to Cymbalta discontinuation or withdrawal are not "discoverable" because they are neither relevant nor "reasonably calculated to lead to the discovery of admissible evidence." *Marin*, 2009 WL 426061, at *1.

IV. A Speculative Punitive Damages Theory May Not Support Irrelevant Discovery

Plaintiffs argue that certain categories of documents — general promotional practices, performance reviews, and documents related to other products — that are encompassed by its requests could support the "potential" application of punitive damages in this case. Pl. Memo. at 12. In Texas, punitive damages may be awarded only if the plaintiff proves by clear and convincing evidence that the harm results from fraud, malice, or gross negligence. Tex. Civ. Prac. & Rem. Code § 41.003. "To recover punitive damages in a products liability case in Texas, a plaintiff must prove that the defendant was consciously, i.e., knowingly, indifferent to his rights, welfare and safety." *Glasscock v. Armstrong Cork Co.*, 946 F.2d 1085, 1093 (5th Cir. 1991) (internal quotation marks omitted). Notably, courts outside of Texas also frequently apply this standard to find claims for punitive damages unfounded where a manufacturer warns of the

potential risk that resulted in the plaintiff's injury, even though that warning might subsequently be determined to be insufficient. *See Salvio v. Amgen Inc.*, No. 2:11-cv-00553, 2012 WL 517446, at *7-8 (W.D. Pa. Feb. 15, 2012) (granting motion to dismiss punitive damages claim where the pharmaceutical label "warned of . . . the very injury that allegedly caused Decedent's death," so that "even if Plaintiff could show that more could have been done or said, the Defendants did not display indifference toward the public's safety") (Pennsylvania law); *Heston v. Taser Int'l., Inc.*, 431 Fed. Appx. 586, 589 (9th Cir. 2011) (upholding a decision to vacate a punitive damages award where "TASER made efforts, albeit insufficiently, to warn its customers about the risks posed by prolonged TASER deployment"); *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1317 (11th. Cir. 2000) ("[T]he issue of punitive damages should not go to the jury when a manufacturer takes steps to warn the plaintiff of the potential danger that injured him; such acts bar a finding of wantonness.") (Alabama law); *Dudley v. Bungee Int'l Mfg. Corp.*, No. 95-1204, 1996 WL 36977, *3 (4th Cir. Jan. 31, 1996) (reversing finding on punitive damages where "[defendant] warned of the potential danger that injured [plaintiff]" and thus "an award of punitive damages was not warranted under a failure to warn theory") (Virginia law); *In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161, 1169 (8th Cir. 2012) (finding punitive damages inappropriate in a pharmaceutical product liability case because "[b]y warning of [the] risk in its package insert, [defendant] actively sought ways to prevent the dangers associated with its product") (internal quotations and citations omitted) (Minnesota law).

As noted above, the warning in Cymbalta's package insert has, at all points in time since its FDA approval, included a warning of symptoms associated with Cymbalta discontinuation, demonstrating Lilly actively sought ways to prevent the dangers associated with its product and was not "consciously . . . indifferent to [Plaintiffs'] rights, welfare and safety." On the basis of

this warning, one federal court has ruled and a unanimous jury has found that the discontinuation warning for Cymbalta is adequate. *Hagan-Brown v. Eli Lilly & Co.*, 1:14-cv-01614-AJT-JFA (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *Ali v. Eli Lilly & Co.*, 1:14-cv-01615 (AJT/JFA) (E.D. Va. Sept. 1, 2015) (jury verdict for Lilly on warning adequacy); *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391 (S.D.N.Y. 2014) (granting judgment for Lilly on adequacy of warning), *reconsideration denied* 2015 WL 845720 (S.D.N.Y. Feb. 26, 2015). Given the unlikelihood of punitive damages in this case, a speculative statement that documents otherwise wholly unrelated to the central issues of the case have "potential" relevance to the applicability of punitive damages should not support the grant of broad and irrelevant discovery.

In addition, although Lilly maintains the discovery sought is irrelevant and unduly burdensome, if the Court is inclined to grant Plaintiffs' motion, Lilly requests that any order direct that Plaintiffs share in the costs. *See, e.g.*, *Multitechnology Servs., L.P. v. Verizon Southwest f/k/a GTE Southwest Inc.*, 2004 WL 1553480, at *2 (N.D. Tex. July 12, 2004) (holding the parties should share the costs of the Plaintiff's requested discovery); *Boeynaems v. LA Fitness Int'l, LLC*, 285 F.R.D. 331, 336-38 (E.D. Pa. 2012) (surveying cost-shifting case law).

Finally, regarding Plaintiffs' statement of their intent to seek production of certain district managers' custodial files, Lilly has yet to receive this request for production and thus cannot address any objections it may have as to relevancy, burden, or privilege. As a result, this planned document request is outside the appropriate scope of a motion to compel and Lilly respectfully requests that this Court decline to address it.

CONCLUSION

For the foregoing reasons, Lilly respectfully asks the Court to deny Plaintiffs' motion to compel production of the complete files of the 13 requested sales representatives, limited only by

time period, and impose reasonable limitations, including the application of search terms to Plaintiffs' requests.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of October, 2015, I served Plaintiffs' counsel in this action with a copy of Defendant's Opposition to Plaintiffs' Motion to Compel by electronic mail to the following addresses:

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